

**REMARKS**

This paper is submitted in response to the Office Action mailed November 14, 2003.

Claims 1-40 are pending. Claims 9-20 and 30-40 have been withdrawn.

**Election Requirement**

The Examiner has made final the election requirement set forth in the Office Communication dated July 2, 2003. The Examiner has indicated that the election is deemed proper, because the Applicants' invention relates to synergistic combinations which require different considerations as to patentability for each combination.

In the Response to Election Requirement dated August 25, 2003, Applicants elected the claims of Group I, having claims directed to a composition containing octoxyglycerin and a biguanide compound. The claims which read on the elected species are claims 1-8 and 21-40. However, Applicants also indicated that the preferable election would be claims directed to a composition comprising octoxyglycerin, a biguanide compound, and a quaternary ammonium compound. Claims 1-8 and 21-29 would read on this elected species.

Instead of considering claims 1-8 and 21-40 (compositions comprising octoxyglycerin and a biguanide compound), the Examiner is considering claims 1-8 and 21-29 (compositions comprising octoxyglycerin, a biguanide compound, and a quaternary ammonium compound). Therefore, it is unclear as to whether the Examiner has made final the election requirement or accepted the Applicants' traversal, since the preferred species (compositions comprising octoxyglycerin, a biguanide compound, and a quaternary ammonium compound) is currently

under consideration. Applicants request clarification regarding status of the traversal of the election.

Furthermore, Applicants submit that upon allowance of generic claim 1, they are entitled to consideration of claims to additional species which are in written in dependent form or otherwise include all limitations of the allowed generic claim.

The Rejection under 35 U.S.C. § 112, ¶1 Should Be Withdrawn

Claims 1-8 and 21-29 have been rejected under 35 U.S.C. § 112, first paragraph, because the specification, according to the Examiner, while being enabling for synergistic compositions, does not reasonably provide enablement to generic compositions. The Examiner acknowledges that the applicants' examples establish a synergistic composition of octoxyglycerin, chlorhexidine digluconate and benzalkonium chloride and that there is a lack of data to support the generic claims 1-8 and 21-29. Therefore, the Examiner further alleges that the specification does not enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants respectfully traverse the rejection. The claimed invention must be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d. at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). Evaluation of undue experimentation involves, but is not limited to the following factors: breadth of the claims, nature of the invention, state of the prior art, level of one of ordinary skill, level of predictability, amount of direction provided by the inventor, existence of working examples and the quantity of

experimentation needed to make or use the invention. *In re Wands*, 858 F2d. at 731, 8 USPQ2d at 1400 (Fed. Cir. 1988). Applicants submit that it would not require undue experimentation to obtain the claimed antimicrobial composition.

First of all, the specification clearly provides considerable guidance for one of skill in the art to make and use the full scope of the claimed composition. Claim 1 recites an antimicrobial composition comprising octoxyglycerin, a quaternary ammonium compound, and an antimicrobial agent<sup>1</sup>, such as, *inter alia*, biguanide compounds. The specification clearly discloses examples of quaternary ammonium compounds, e.g. benzalkonium chloride (BZK) and benzethonium chloride (BZT), at page 8 para. 0022. Examples of biguanide compounds are also disclosed, e.g. chlorhexidine digluconate (CHG) and polyhexamethylene biguanide (PHMB), at page 8, para. 0019. Furthermore, working examples include compositions comprising (1) octoxyglycerin, BZK, and CHG (Table 6, page 26), (2) octoxyglycerin, BZK, and PHMB (Table 8, page 29), and (3) octoxyglycerin and BZT (Table 5, page 25). By the disclosure of various examples of quaternary ammonium and biguanide compounds and their use in working examples, the specification clearly sets forth sufficient alternative compounds to support the generic claims.

Secondly, all the methods needed to practice the present invention are well known. Antimicrobial activity is measured by adding test gels comprising the various claimed composition to a fixed number of bacterial cells, which are plated and incubated. The plates

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<sup>1</sup> An enabling disclosure of other antimicrobial agents is also provided by the specification, e.g. triclosan at page 7, para 0020, Tables 5-7; phenoxyethanol at page 7, para 0020, Tables 8-14; iodine compounds at page 8, para 0021; and parachlorometaxyleneol at page 7, para 0020, page 24, para 0033, Tables 5-7.  
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were evaluated for colony forming units per tube after incubation. This assay is straightforward and conventionally used in the art. There is also high skill in the art at the time the application was filed. Therefore, Applicants submit that there is considerable direction and guidance in the specification for one of skill in the art to make and use the claimed compositions.

Given the level of skill in the art and the disclosure of various types of quaternary ammonium and biguanide compounds, Applicants submit that no undue experimentation would be required make and use the full scope of the antimicrobial compositions recited in generic claims 1-8 and 21-29. Applicants respectfully request withdrawal of the rejection of claims 1-8 and 21-29 under 35 U.S.C. § 112, first paragraph.

The Rejections under 35 U.S.C. § 103(a) Should Be Withdrawn

Claims 1-8 and 21-29 have been rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over United States Patent No. 6,613,312 by Rizvi et al. ("Rizvi") in view of United States Patent No. 6,022,551 by Jampani et al. ("Jampani") and United States Patent No. 6,420,431 by Johnson ("Johnson"). The Examiner alleges that Rizvi teaches that octoxyglycerin and quaternary ammonium are known antimicrobial compounds, and acknowledges that Rizvi does not teach a biguanide compound. The Examiner alleges that Jampani disclose chlorhexidine digluconate and an alcohol as components of an effective "skin friendly" antimicrobial composition. The Examiner also alleges that it would have been prima facie obvious to combine the antimicrobial composition of Rizvi with an antimicrobial composition of chlorhexidine in alcohol.

Applicants disagree. To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine the teachings. The teaching or suggestion to make the claimed combination must both be found in the prior art and not based on Applicant's disclosure. *In re Vaeck* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1981).

There is no suggestion or motivation in either Rizvi or Jampani to modify the references or to combine the teachings to obtain an antimicrobial composition comprising octoxyglycerin, a quaternary ammonium compound, and an antimicrobial agent, such as a biguanide compound. Rizvi relates to an effective antiperspirant product that retains a high degree of stability comprising an antiperspirant active material, a silicone or hydrocarbon carrier, and a suspending agent. Rizvi provides a laundry list of suitable antiperspirant active materials, including octoxyglycerin and a quaternary ammonium compounds. However, Rizvi does not teach that octoxyglycerin and a quaternary ammonium compounds may be used in combination. As indicated by the Examiner, Rizvi also fails to teach the use of biguanide compounds. Furthermore, there is no suggestion or motivation provided in Rizvi that more than one antiperspirant active material would be required. Therefore, one of skill in the art would not be motivated to make the combination of agents of the presently claimed composition or seek other references that would suggest the combination of agents of the presently claimed composition.

In contrast to Rizvi, Jampani relates to disinfecting compositions that may be used for disinfection of surfaces, such as hands. Jampani discloses that primary antimicrobials, alcohol,

triclosan, phenoxyethanol, and possibly the quaternary ammonium compounds, benzalkonium chloride or benzethonium chloride may be used. Additional antimicrobials, such as chlorhexidine gluconate, may optionally be added to these compositions. However, Jampani also cites antibiotic resistance as a motivation against the use of antibiotic compounds, such as chlorhexidine gluconate (col. 1, lines 18-24). In fact, the fear of emerging antibiotic resistance strains of bacteria in a hospital environment would deter the skilled artisan from designing compositions comprising multiple antimicrobial agents, as in the presently claimed compositions. Furthermore, Jampani compares their disclosed compositions to other products that contain high levels of chlorhexidine gluconate (col. 3, lines 28-34), suggesting that the preferred embodiment does not contain chlorhexidine gluconate. Therefore, Applicants submit that Jampani, as a whole, teaches away from the addition of biguanide compounds, such as chlorhexidine gluconate, to an antimicrobial composition.

In addition, Jampani fails to disclose the use of octoxyglycerin. The use of octoxyglycerin is conventionally used in deodorant compositions to eliminate odor-causing Gram-positive bacteria. Given that Jampani discloses compositions that possess immediate and persistent activity (col. 3, lines 25-28) and are effective against a broad spectrum of organisms, including Gram-negative and Gram-positive bacteria, yeast and fungi (col. 3, lines 47-50), Jampani provides no motivation to one of skill in the art to supplement the antimicrobial activity of the disclosed compositions with additional antimicrobial or antibiotic agents. For the foregoing reasons, Applicants submit that Jampani does not motivate one of skill in the art to make the combination of components of the presently claimed composition.

Furthermore, the presently claimed compositions exhibit a synergistic antimicrobial effect, as acknowledged by the Examiner. The observed synergistic effects of the combined agents in the presently claimed compositions surpass reasonable expectations of one of skill in the art. For example, the combination of octoxyglycerin (1.0%), CHG (0.05%) and BZK (0.12%) results in the growth of  $4 \times 10^4$  cfu/tube from  $10^8$  cells (Table 8), whereas each of the agents added to the same number of cells produces  $1.0 \times 10^7$  cfu/tube (octoxyglycerin (1.0%)),  $1.1 \times 10^7$  cfu/tube (CHG (0.05%)) and  $1.6 \times 10^7$  cfu/tube (BZK (0.12%)), respectively. One of skill in the art would not have expected such a dramatic decrease in the number of surviving cells from the introduction of the triple combination. Therefore, the combination of the three agents in the presently claimed composition confer unexpected antimicrobial activity. For this additional reason, Applicants submit that claims 1-8 and 21-29 are not obvious over Rizvi in view of Jampani.

The Examiner has also cited Johnson in the Office Action, but has not provided specific comments regarding unpatentability of claims 1-8 and 21-29. Applicants request that the Examiner clearly set forth reasons as to how Johnson relates to the patentability of the pending claims.

#### Information Disclosure Statement

Applicants submit herewith a copy of the PTO Form 1449, previously forwarded on January 8, 2003. Applicants respectfully request the Examiner to consider the listed references, initial the PTO Form 1449, and return a copy of the initialed form to the undersigned attorney.

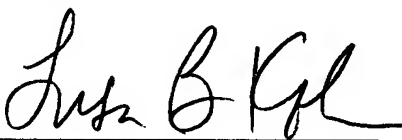
**CONCLUSION**

In view of the foregoing remarks, Applicants respectfully request withdrawal of the outstanding rejections and allowance of the pending claims.

Applicants request a two month extension of time and enclose herewith the requisite fee as set forth in 37 C.F.R. § 1.17(a)(2). Applicants do not believe that any additional fee is required in connection with the submission of this document. However, should any fee be required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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